

A SUMMARY OF THE NBCCEDP CERVICAL CANCER SCREENING REIMBURSEMENT POLICIES EXPERT PANEL RECOMMENDATIONS AS PRESENTED IN THE WHITE PAPER ON TECHNOLOGIES FOR THE EARLY DETECTION OF CERVICAL CANCER

Background

An independent expert panel composed of representatives (16) from academia, industry, professional organizations, clinicians, public health practitioners and other federal agencies was charged with: a) identifying minimum criteria for establishing new reimbursement policies, b) identifying a framework of issues to be considered in policy review, c) providing specific recommendations for reimbursement policies, and d) providing guidance concerning procedures for future reviews of reimbursement policies. Members of the expert panel conferred in subgroups and as a full committee through a series of conference calls and a face-to-face meeting. The following cervical cancer screening technologies were reviewed:

- **Conventional cytology**
- **Liquid-based cytology**
- **HPV testing** (as a *replacement of* and as *an adjunct to* screening cytology)

REIMBURSEMENT DECISION CRITERIA

Panel members established decision criteria for each technology: Because screening is performed on healthy, asymptomatic women, each new technology must clearly demonstrate its ability to perform equally to or better than current technologies and must meet minimum criteria. That is, each newer technology must:

- reduce breast cancer morbidity and mortality
- sustain or enhance the number of program eligible women served by the NBCCEDP
- sustain or enhance overall quality of care
- sustain or enhance overall program operations
- reduce overall health disparities

Beyond these minimum criteria, policies must accommodate differences across programs and remain consistent across programs while still affording flexibility in implementation by local NBCCEDP programs. In addition, as a federal government agency, the CDC must consider related policies established by other federal agencies, in particular the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS).

BASIS FOR TECHNOLOGIES ASSESSMENT

The basis for decisions about whether the NBCCEDP should provide reimbursement for any new technology combines a full range of test characteristics as well as program factors and is unique to each technology. The test characteristics used in this evaluation were performance, frequency (interval), and test costs (lab costs). In addition to test characteristics, program, patient, and clinical factors were taken into consideration.

CERVICAL CANCER SCREENING RECOMMENDATIONS

Following careful review of the test characteristics and public health factors associated with each technology, the NBCCEDP Expert Panel on Cervical Cancer Reimbursement Policies discussed potential policies and reached consensus on specific recommendations. An overview of these recommendations and key rationale points for each are presented below.

- **Conventional Cytology**
Recommendation: Continue reimbursement of conventional cytology annually and every three years for women with three consecutive normal Pap tests within a five year period. (Recommendation mirrors the current policy.)

Rationale: No new evidence has emerged to warrant a change in the existing policy. Morbidity and mortality from cervical cancer have declined substantially since the introduction of conventional cytology. Conventional cytology is well integrated into existing clinical practice. Conventional cytology is well accepted among patients.

- **Liquid-based cytology**

Recommendation: Allow reimbursement for biennial screening with liquid-based cytology (LBC)-as opposed to annual screening with conventional cytology. (Recommendation differs from the current policy. Currently, the CDC policy reimburses liquid based cytology at the conventional reimbursement rate only.)

Rationale: Test administration similarities between LBC and conventional cytology make patient acceptability of LBC high. No additional provider time or training is required for administering LBC, making clinical efficiency for LBC high. While some additional supplies might be required, these should be covered under Medicare LBC reimbursement rates. Ease of HPV triage enhances both clinical efficiency and patient adherence and acceptability because requirements for repeat patient visits are reduced. Increased sensitivity and decreased specificity are associated with this screening technology.

- **HPV testing**

Recommendation: Reimbursement for combined cytology and HPV testing among normal, asymptomatic women is not recommended at this time. Reimbursement for HPV testing as an option for follow-up of ASC-US cytology is recommended. (Recommendation mirrors the current policy.) HPV testing recommendations should be reviewed in one year to consider findings soon to be published from general population screening studies assessing cytology and HPV testing in a large health maintenance organization.

Rationale: Insufficient evidence exists to support HPV testing as an alternative or adjunct to primary cytology screening. While HPV testing may have a future screening role in distinguishing between women who would benefit from more intensive cytology testing and those for whom screening can be less intensive or even discontinued, current evidence does not support the benefits of such HPV-based risk assessment and triage at this time. Ongoing randomized trials on HPV testing should provide additional evidence on these issues over the next several years. Use of HPV as an alternate or adjunct screening test would trade-off testing for higher prevalence HPV versus lower prevalence abnormal cytology. The morbidity and mortality consequences of this trade-off are unknown. Further, such a trade-off could result in higher follow-up rates and associated program and patient costs. Considerable patient and provider education would be required concerning the epidemiology of high-risk HPV, its relationship to cervical cancer, and the benefits and shortcomings of HPV testing. While provider and direct-to-consumer marketing is likely to increase demand for HPV testing as an alternative or adjunct to cervical cytology, current levels of market penetration are low.

Research and Surveillance Recommendations

In addition to specific screening reimbursement policy recommendations, the panel presented recommendations for demonstration projects to assess:

- cost/benefit and implementation challenges of biennial LBC
- patient and provider perceptions and behavior related to extended screening intervals
- extent of clinical practice adherence to screening guidelines (e.g., intervals, age, etc.), reasons for deviations, and practice differences between NBCCEDP and non-program patients
- provider and laboratory practices in the use of LBC and HPV testing

Provider Education Recommendations

In addition to specific screening reimbursement policy and demonstration project recommendations, the panel also provided provider education recommendations to increase understanding of

- the potential harms of low test specificity/high false positive rates
- the relationship of test intervals to test and disease characteristics.

Policy Review Recommendations

The panel also recommended that the CDC conduct an annual assessment of whether new evidence and/or technologies have emerged that alter clinical practice and could change current reimbursement policies.

The panel recommended that in the event that it is determined that practice altering technologies have emerged, an expert panel review of policies should be conducted. Finally, the panel recommended a full policy review at least every 5 years. Naturally, reviews should be informed by the evidence reviews conducted by the USPSTF to prevent duplication of effort.

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